National Cancer Institute

Standard Operating Procedure

SUBJECT: Electronic Loading of Common Data Elements (CDEs) under the caBIG™ Program	SOP No.: IT-004
	Version No.: 2.0
	Effective Date: 12/11/2006
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Standard Operating Procedure –

Electronic Loading of Common Data Elements under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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Department Approval:

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Chief Operating Officer, NCICB

QA Approval:

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Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

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Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.

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1. Purpose

This Standard Operating Procedure (SOP) describes the process for the loading of common data elements (CDEs) into NCICB's clinical data management system.

2. Scope

2.1   This SOP will be used for the loading of all CDE's for clinical trials research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

2.2   This SOP applies to the electronic loading of CDEs from the Cancer Data Standards Repository (caDSR).

3. Requirements

3.1   CDEs must remain in the predefined format as represented in the caDSR Repository.

3.2   The CDE electronic file located in the CDE Staging area from a previous data load must be archived.

3.3   A documentation trail must be maintained for CDEs loaded electronically into the NCICB clinical data management systems.

3.4   Quality control procedures should be applied at every stage of the loading process to assure that all CDE records are reliable and have been processed correctly.

3.5   A formal process should be in place to handle: The deletion or back-out of a CDE file that has been loaded incorrectly (either a full or partial load); missing values; or duplicate records.

3.6   All staff responsible for filling the roles identified in the Roles and Responsibilities section will receive training on this SOP.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	CR-004	SOP for CDE Curation
4.3	N/A	CDE Loader Utility Usage Guide
4.4	N/A	HL7 Working Group. *An Application Protocol for Electronic Data Exchange in Healthcare Environments.* Health Level Seven, Inc.

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5. Roles & Responsibilities

Role	Responsibility
caDSR Curator	• Prepare the CDE load export file.
CDE Loader Technician	• Prepare the CDE file for loading. • Prepare the application's standards library for load. • Perform the technical load of the CDE file into the clinical data management application's standards library.
Help Desk	• Problem analysis and resolution for issues encountered during the loading process. • Refer significant problems to appropriate Loader Technician.
NCICB Applications Director	• Authorize any backing out of data.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Electronic Loading of CDEs under the caBIG™ Program	This document provides instructions for loading CDEs. This procedure also includes load back-out procedures, re-loads and management and resolution of partial load results.
2) CDE Load Check Sheet	This document provides a user friendly checklist for the loading of CDEs.
3) Process Flow for Electronic Loading of CDE's	This document graphically depicts the activities, by role, in performing electronic loading of CDE's.